510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k123725

B. Purpose for Submission:

New device

C. Measurand:

Multi-analyte control material for Free Thyroxine (FT4), Human Chorionic Gonadotropin (hCG), Testosterone, Total Prostate Specific Antigen (tPSA), and Thyroid Stimulating Hormone (TSH)

D. Type of Test:

Not applicable

E. Applicant:

Qualigen, Inc.

F. Proprietary and Established Names:

FastPack Control Kit

G. Regulatory Information:

Regulation Section	Classification	Product Code	Panel
21 CFR § 862.1660	Class I, reserved	JJY, multi-analyte controls, all kinds (assayed)	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   Refer to Indications for Use below.

2. Indication(s) for use:

   The FastPack Control Kit is an assayed quality control for the verification of the accuracy and precision of the FastPack System and FastPack IP Systems when used for the quantitative determination of the analytes listed in the package insert. The following analytes are included in the package insert:

   - Free Thyroxine (FT4)
   - Human Chorionic Gonadotropin (hCG)
   - Testosterone
   - Total Prostate Specific Antigen (tPSA)
   - Thyroid Stimulating Hormone (TSH)

3. Special conditions for use statement(s):

   For in vitro diagnostic use.

   For prescription use only.

4. Special instrument requirements:

   FastPack System

I. Device Description:

The FastPack Control Kit consists of a low and high control. Each control is prepared from bovine serum albumin (BSA) as the primary protein source and to provide a viscosity similar to human serum. Other components added include constituents of human origin, stabilizers, inhibitors, and preservatives. Added analyte materials (hCG, TSH, FT4, Testosterone, and PSA) are purchased commercially. The controls are supplied in ready to use liquid form and packaged in a 5 mL bottle each.

All human source materials were tested and found to be negative for, HIV ½, HBV, and HCV using FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Immunology Control (containing FT4, testosterone, and hCG)
   FastPack® Controls (containing PSA)
   FastPack® TSH Controls

2. Predicate 510(k) number(s):

k960824
k003095
k052301

3. Comparison with predicate:

Similarities			
Item	Device FastPack® Control Kit	Predicate 1 Immunology Control (containing FT4, testosterone, and hCG) (k960824)	Predicate 2 and 3 FastPack® Controls for PSA (k003095) and FastPack® TSH Controls (k052301)
Intended Use	Same	Assayed quality control for the verification of the accuracy and precision of the analytes listed in the package insert.	Assayed quality control for the verification of the accuracy and precision of the analytes listed in the package insert
Form	Same	Liquid	Liquid
Fill Volume	Same	5 mL	5 mL

Differences			
Item	Device FastPack® Control Kit	Predicate 1 Immunology Control (containing FT4, testosterone, and hCG) (k960824)	Predicate 2 and 3 FastPack® Controls for PSA (k003095) and FastPack® TSH Controls (k052301)
Matrix	Synthetic	Human Serum	Bovine Serum Albumin
Opened Vial Stability at 2 – 8°C	120 days	30 days	9 months
Shelf Life Stability	18 months at 2 – 8°C	3 years at -20°C	12 months at 2 – 8°C

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability

The analytes contained in the FastPack Control Kit were obtained from commercially available sources and are traceable to commercially available standards.

Stability

Shelf-life and open-vial stability protocols and acceptance criteria were reviewed and found to be acceptable. The closed vial (shelf-life) stability claim at the recommended storage temperature of 2 to 8 °C is 18 months based on ongoing real-time studies. The opened vial stability claim at the recommended storage temperature of 2 to 8 °C is 120 days based on real time data.

Value Assignment

Values are assigned to the calibrators based on replicate analysis using six FastPack analyzers, three reagent lots, and two calibrations. The sponsor calculates a range based on ± 3 standard deviations from the mean for each level for each analyte, but states that each laboratory should establish their own acceptable ranges.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

*b. Clinical specificity**:***

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Expected values are provided in the value assignment sheets provided with the package insert.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.